March 12, 2021

Schoelly Fiberoptic GmbH
% Pamela Papineau, RAC
Regulatory Affairs Consultant (Alternate Application Contact)
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432

Re: K201617
Trade/Device Name: TipVision Videoscope System (TipVision VideoScope 0º/30º; EleVision HD 2 Camera Control Unit (CCU))
Regulation Number: 21 CFR§ 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Product Code: HET, GCJ, FET
Dated: February 4, 2021
Received: February 5, 2021

Dear Pamela Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For
Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201617

Device Name
TipVision Videoscope System (TipVision VideoScope 0°/30°; EleVision HD 2 Camera Control Unit (CCU))

Indications for Use *(Describe)*
The TipVision 0º/30º Videoscopes and EleVision HD 2 CCU are indicated for visualization during general laparoscopy, gynecological laparoscopy, urological laparoscopy, and video-assisted minimally invasive thoracic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

A. GENERAL INFORMATION

510(k) Sponsor:	Schoelly Fiberoptic GmbH
Address:	Robert-Bosch-Str. 1 – 3 79211 Denzlingen Germany
FDA Registration Number:	8043903
Telephone Number:	+49-7666-980-0
Fax Number:	+49-7666-908-380
Contact Person:	Dr. Sandra Baumann
Date Prepared:	11 March 2021

B. DEVICE IDENTIFICATION:

Trade/Device Name:	**TipVision™ Videoscope System (TipVision Videoscope 0º/30º; EleVision HD 2 Camera Control Unit (CCU))**
Regulation Name:	Gynecologic Laparoscope And Accessories
Regulation Number:	21 CFR 884.1720 (Gynecologic Laparacope and Accessories)
Product Code:	HET (laparoscope, gynecologic (and accessories)) GCJ (laparoscope, general & plastic surgery) FET (endoscopic video imaging system/component, gastroenterology-urology)
Regulatory Class:	Class II

C. PREDICATE DEVICES:

Predicate 1 - Videoscope

Trade Name:	EndoEYE HD II Videoscope;
510(k) Sponsor:	Olympus America, Inc.
510(k) Number:	K111788

Recall: The Endoeye HD II Video Telescope cleared in predicate K111788 was the subject of a class II design related recall due to a damaged temperature sensor in the distal end of the endoscope. The issue has been successfully resolved and design changes have been cleared via K190744. The installed heating element warms the distal tip to minimize or eliminate fogging of the lens during the procedure and aids in the prevention of endoscope removal to clean the lens due to fogging during a procedure. The TipVision Videoscope System does not include this feature.

Predicate 2 – Camera Control Unit

Trade Name:	Visera Elite Video System Center (OTV-S190)
Sponsor:	Olympus Medical Systems Corp.
510(k) Number:	K111425

There were no design-related recalls associated with this device.

D. DEVICE DESCRIPTION:

The TipVision™ Videoscope System, consisting of the TipVision 0° / 30° Videoscope and the EleVision™ HD 2 Camera Control Unit (CCU), is used for 2D visualization of anatomical structures of the human body during endoscopic surgery including general laparoscopy, gynecological laparoscopy, urological laparoscopy, and video-assisted minimally invasive thoracic surgical procedures. The TipVision™ Videoscope can only be used with the EleVision™ HD 2 CCU; this combination of videoscope and camera controller results in a camera based on complementary metal–oxide–semiconductor (CMOS) technology with LED illumination. When used with a compatible monitor, the camera delivers a native full HD image resolution using progressive scanning (1080p). All parameters that can be adjusted through the user interface of the CCU (magnification, illumination brightness, saturation, selective color enhancement, color shift, image storage, etc.) can also be controlled by the buttons on the TipVision™ Videoscope.

The TipVision™ Videoscope is connected to the EleVision™ HD 2 CCU by means of a cable attached to the scope handpiece. The user has the ability to adjust videoscope imaging parameters using the buttons on the videoscope handle, or via the CCU. The EleVision™ HD 2 CCU is available in two configurations: image recording only, or image and video recording.

E. INDICATIONS FOR USE:

The TipVision™ 0°/30° Videoscopes and EleVision™ HD 2 CCU are indicated for visualization during general laparoscopy, gynecological laparoscopy, urological laparoscopy, and video-assisted minimally invasive thoracic procedures.

F. COMPARISON OF SUBJECT DEVICE TECHNILOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

A comparison of the technicological characteristics was conducted between the subject device and two predicate devices, one for the videoscope (Olympus EndoEYE HD II videoscope cleared under K111788) and one for the CCU (Olympus Visera Elite Video System Center cleared under K111425). A detailed comparison of the subject and predicate devices is provided in the table below.

Technological Characteristics Comparison Table - Videoscope

Attribute	Proposed TipVision 0° / 30° Videoscope (current submission)	Predicate Device Olympus EndoEYE HD II (K111788)	Similarities and Differences
Indications for Use	The TipVision™ 0°/30° Videoscopes and EleVision™ HD 2 CCU are indicated for visualization during general laparoscopy, gynecological laparoscopy, urological laparoscopy, and video-assisted minimally invasive thoracic surgical procedures.	This instrument has been designed to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical instrument, and other ancillary equipment for endoscope and endoscopic surgery within the thoracic and abdominal cavities including the female reproduction organs	Different indications for use; Same intended use: visualization during general laparoscopic / endoscopic, gynecological, urological, and thoracic surgical procedures
Use Environment	Hospital, clinic, medical office	Hospital, clinic, medical office	Same
System Components	TipVision™ Videoscope (rigid video endoscope)	Olympus Endoeye HD 2 Videoscope (rigid video endoscope)	Same
Principle of Operation	Rigid videoscope with imaging chip in distal tip; wired connection between videoscope and CCU	Rigid videoscope with imaging chip in distal tip; wired connection between videoscope and CCU	Same
Light Source	Integrated LEDs in endoscope tip, powered by CCU	External light source connected to the endoscope, light transmission through endoscope via fiber optics	Different technology; same performance
Image Transmission	CMOS chip in scope tip	CCD chip in scope tip	Different technology; same performance
Direction of View	0°, 30°	0°, 30°	Same
Field of View	76°	72°, 80°, 90°	Similar; within predicate range
Tip Rotation	170°	N/A	Different
Depth of Field	20 mm – 200 mm	20 mm – 200 mm	Same
Image Resolution	Full HD (1080)	Full HD (1080)	Same
Insertion Tube Working Length	341 mm	300 mm – 330 mm	Similar
Insertion Tube Outer Diameter	10 mm	5.4 mm, 10 mm	Same; within predicate range

Scope Internal Channels	None	None	Same
Scope Power Source	Wired connection between videoscope and CCU	Wired connection between videoscope and CCU	Same
Control Buttons on Scope Handpiece	Yes, user-configurable	Yes, user-configurable	Same
Biocompatibility	Yes	Yes	Same
Single Use / Reusable	Reusable	Reusable	Same
Scope Reprocessing	Cleaning (manual or automated) and steam sterilization	Cleaning (manual or automated), steam sterilization	Same
Scope Moisture Resistance	IPX 7	IPX 7	Same
Electrical Safety & Thermal Safety	Yes	Yes	Same
Electromagnetic Compatibility	Yes	Yes	Same
Scope Safety Performance	Yes	Yes	Same

Technological Characteristics Comparison Table – Camera Control Unit

	Proposed TipVision™ Videoscope System (current submission)	**Predicate Device Olympus Visera Elite Video System Center and Light Source (K111425)**	**Similarities and Differences**
Indications for Use	The TipVision™ 0°/30° Videoscopes and EleVision™ HD 2 CCU are indicated for visualization during general laparoscopy, gynecological laparoscopy, urological laparoscopy, and video-assisted minimally invasive thoracic surgical procedures.	Visera elite video system center: this video system center has been designed to be used with olympus camera heads, endoscopes, light sources, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation. Visera elite xenon light source: this light source has been designed to be used with olympus endoscopes, video system center, and other anciallary equipment for endoscopic diagnosis,	Different indications for use; Same intended use: visualization during general laparoscopic / endoscopic, gynecological, urological, and thoracic surgical procedures

		treatment and video observation.	
Use Environment	Hospital, clinic, medical office	Hospital, clinic, medical office	Same
Principle of Operation	CCU provides power to videoscope and performs video image processing; image can be viewed on a compatible video monitor	CCU provides power to videoscope and performs video image processing; image can be viewed on a compatible video monitor	Same
Single Use / Reusable	Reusable	Reusable	Same
Software	Yes	Yes	Same
Electrical Safety & Thermal Safety	Yes	Yes	Same
EMC	Yes	Yes	Same

Differences in technological characteristics do not raise different questions of safety and effectiveness.

A. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING:

Reprocessing:

Reprocessing validations weredesigned and conducted in accordance with FDA's 2015 guidance (including Appendix E revised June 2017) *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.*

Cleaning studies were designed and performed in accordance with AAMI TIR12:2010 *Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers*, AAMI TIR30:2011(R)2016 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable devices*.

Sterilization studies were designed and performed in accordance with AAMI TIR12:2010 *Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers*, and ANSI/AAMI/ISO 17665-1:2006 (R)2013 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*. Cleaning and sterilization processes are defined in the device labeling per ISO 17664:2017 *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices*.

These tests demonstrated that the device successfully passed cleaning, drying and sterilization validations according to the instructions in the user manual.

Biocompatibility:

The patient contacting component of the subject device system is the videoscope insertiontube. The contact category for this component is Tissue/Bone/Dentin Communicating, ≤24 hours.

The videoscope insertion tube was evaluated and tested for biocompatibility in accordance with the following standards and the FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process":

- ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- ISO 10993-5:2009 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10:2010 *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11:2017 *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- 42-NF37:2019 *USP <151> Pyrogen Test (USP Rabbit Test)*

Performance Testing:

Optical performance (direction of view, field of view, distortion/resolution, luminous flux, color performance, photobiological safety), optical safety, and thermal safety testing were conducted in accordance with the standards listed below:

- ISO 8600-1:2015 *Medical endoscopes and endotherapy devices – Part 1: General requirements*
- ISO 8600-3:2019 *Medical endoscopes and endotherapy devices – Part 3: Determination of Field of View and Direction of View of Endoscopes with Optics*
- ISO 8600-5:2005 *Optics and photonics – Medical endoscopes and endotherapy devices – Part 5: Determination of Optical Resolution of Rigid Endoscopes with Optics*
- IEC 62471:2006 (First Edition) *Photobiological safety of lamps and lamp systems*
- IEC 60601-2-18:2009 *Medical electrical equipment, Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*

The following additional testing was performed by the sponsor in support of device performance:

- Usability testing per IEC 60601-1-6:2016
- Noise and Dynamic Range testing
- Mechanical testing for the tip rotation

Software Documentation:

Software documentation for a Moderate Level of Concern device is provided in support ofthe subject device per FDA's 2005 *Guidance for the Content of Premarket Submissions for Software Contained in Medical Device*. The software lifecycle, including software documentation and validation, is managed in accordance with IEC 62304:2006/A1:2016 *Medical Device Software – Software Life Cycle Processes*.

Electrical Safety Testing:

The TipVision™ Videoscope System was assessed for conformity with, and was found to comply with, the relevant requirements of IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (ed. 3.1, including the US deviations) *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.*

The TipVision™ Videoscope System was assessed for conformity with, and was found to comply with, the relevant requirements of IEC 60601-2-18:2009 (3rd edition): *Particular requirements for the basic safety and essential performance of endoscopic equipment.*

Electromagnetic Compatibility Testing:

The TipVision™ Videoscope System was assessed for conformity with, and was found to comply with, the relevant requirements of IEC 60601-1-2 (4th Edition) *Medical electrical equipment, Part 1-2: General requirements for safety – Collateral standard: Electromagnetic Compatibility – Requirements and tests*.

B. CONCLUSION

The performance testing summarized above support a substantial equivalence determination. The performance testing demonstrate that the subject device is as safe and as effective as the legally marketed predicate devices.